# Congress of the United States
## U.S. House of Representatives
## COMMITTEE ON WAYS AND MEANS
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

May 20, 2008

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building
Washington, DC 20201

Dear Acting Administrator Weems:

**As a follow up to the Ways and Means Health Subcommittee Hearing on DME Competitive Bidding on Tuesday, May 6, 2008; please respond to the following Questions for the Record.**

**Questions from Chairman Stark**

(1) As CMS moves to forward with Round 2, it is unrealistic to expect individual suppliers to serve the entire region of the larger MSAs such as New York, Chicago and Los Angeles. Do you expect individual suppliers to be able to service those larger MSAs? If not, do you plan on subdividing the larger MSAs into more manageable areas?

(2) We have heard that some suppliers who were awarded contracts under Round One of the competitive bidding program will attempt to subcontract with other suppliers. While we understand that the suppliers who CMS has contracted with are subject to accreditation standards, it is not clear whether subcontractors will also need to be accredited. Considering that these subcontractors will not be billing Medicare directly, but instead providing items and services to the main contractor, it seems a gap may exist in the accreditation requirements. Could you please clarify what the accreditation requirements are for subcontractors?

**Questions from Rep. Ron Kind**

(1) How will CMS determine which rural areas will be exempted from the competitive bidding program? Has that determination already taken place? If not, when will it be conducted and what specific information will CMS rely on to make such a determination?

(2) What factors will CMS use to determine when and how it will exercise its authority under Social Security Act (SSA) § 1834(a)(1)(F)(ii) (for DME), SSA § 1834(h)(1)(H)(ii) (for off-the-shelf orthotics), and SSA § 1842(s)(3)(B) (for enteral nutrients, supplies, and equipment), which allow the agency to apply prices from winning bids in other MSAs around the country to rural areas?

# Congress of the United States
## U.S. House of Representatives
## COMMITTEE ON WAYS AND MEANS
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

May 23, 2008

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 314-G, Hubert H. Humphrey Building
Washington, DC 20201

Dear Acting Administrator Weems:

**As a follow up to the Ways and Means Health Subcommittee Hearing on DME Competitive Bidding on Tuesday, May 6, 2008; please respond to the following Questions for the Record.**

**Questions from Rep. Sam Johnson**

(1) In the Final Rule issued April 2, 2007, CMS permits physicians to furnish certain types of competitively bid items without submitting a bid and winning a contract. These items include crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors and infusion pumps, but do not include off the shelf orthotics. However, the rule does allow physical and occupational therapists to provide off the shelf orthotics to their patients without participating in competitive bidding because "we have determined that these items would ordinarily be furnished as an integral part of occupational or physical therapy services." Why is there a separate standard for physicians and physical therapists and is there a legitimate concern that this may compromise the ability of physicians to provide medically necessary orthotics to their patients. Why did CMS choose to create a separate standard for physicians and is the agency considering a way to correct this problem?

(2) The Final Rule requires physicians to become accredited in order to supply any orthotics to their patients in the Medicare program. Due to the cost and paperwork required it is likely that many physicians will likely choose not to become accredited, this will then raise some questions about how beneficiaries will receive medically necessary orthotics. In a separate rule relating to Medicare DMEPOS supplier standards released on January 25, 2008, the agency proposes

an across-the-board prohibition on suppliers sharing a practice location with other suppliers—including physicians and other health care practitioners. Physicians at times need to dispense medically necessary DMEPOS items immediately to a Medicare beneficiary—like stabilizing braces, or immobilizing devices. Isn't there a concern that this proposed rule, when considered in conjunction with the new requirements on physicians under competitive bidding, could deny Medicare beneficiaries the ability to receive these medically necessary items when they need them?

**Additional Written Questions**
**Ways & Means Health Subcommittee Hearing**
**On**
**"DME Competitive Bidding"**
**May 6, 2008**

## Chairman Stark

1. As CMS moves forward with Round 2, it is unrealistic to expect individual suppliers to serve the entire region of the larger MSAs such as New York, Chicago and Los Angeles. Do you expect individual suppliers to be able to service those larger MSAs? If not, do you plan on subdividing the larger MSAs into more manageable areas?

   **Answer:** We agree that it is important to apply the bidding rules in a way that is practical for suppliers, and ensures beneficiaries' access to services. The statute requires that we expand the program to an additional 70 of the largest MSAs in the country in 2009. As part of this expansion, CMS has selected the three largest MSAs (New York, Chicago, and Los Angeles) to participate in Round 2 of the competitive bidding program.

   While we have selected these MSAs for Round 2, we have not yet identified the actual competitive bidding areas (CBAs) within these large metropolitan areas. For Round 1, we identified actual bidding areas by zip codes in order to ensure a cohesive market area within each MSA that did not include noncompetitive areas of low population density (relative to the rest of the MSA). CMS expects to perform this same type of analysis as we look at New York and the other areas selected. As a result, the actual CBA may be smaller than the entire MSA, as permitted under the competitive bidding statute. We expect the competitive bidding program will result in real savings for beneficiaries in New York and the other areas selected for both Rounds 1 and 2.

2. We have heard that some suppliers who were awarded contracts under Round 1 of the competitive bidding program will attempt to subcontract with other suppliers. While we understand that the suppliers who CMS has contracted with are subject to accreditation standards, it is not clear whether subcontractors will also need to be accredited. Considering that these subcontractors will not be billing Medicare directly, but instead providing items and services to the main contractor, it seems a gap may exist in the accreditation requirements. Could you please clarify what the accreditation requirements are for subcontractors?

   **Answer:** The competitive bidding contract requires contract suppliers to maintain compliance with all applicable quality standards and accreditation requirements. Each contract supplier is responsible for fulfilling all of the terms of the contract, even if it uses one or more subcontractors. If a contract supplier breaches its contract due to its subcontractor's failure to perform, the contract supplier will be held liable for the breach. The accreditation organization reviews contracted services that a supplier may be using, thus

ensuring that the contract supplier is in compliance with quality standards, including those services provided by subcontractors. Because contract suppliers are held responsible for ensuring that services meet the quality standards, subcontractors are not specifically required to be accredited. Finally, we note that a supplier may not subcontract with any supplier that has been excluded from the Medicare program, any State health program, or any government executive branch procurement or non-procurement activity.

**Rep. Ron Kind**

1. How will CMS determine which rural areas will be exempted from the competitive bidding program? Has that determination already taken place? If not, when will it be conducted and what specific information will CMS rely on to make such a determination?

   **Answer:** The statute provides discretionary authority for exempting low population density areas within urban areas (MSAs) and rural areas (areas outside MSAs) that "are not competitive" unless there is a significant national market through mail order.

   In the final rule, we indicated that we will use this authority if data indicated that an area was not competitive based on one or more of the following indicators:

   a. Low utilization of items in terms of number of items and/or allowed charges for DMEPOS in the area relative to other similar geographic areas;
   b. Low number of suppliers of DMEPOS subject to competitive bidding serving the area relative to other similar geographic areas; and
   c. Low number of Medicare beneficiaries receiving fee-for-service benefits in the area relative to other similar geographic areas.

   For Round 1, we used the discretionary authority in section 1847(a)(3) of the Social Security Act (SSA) to exempt a large portion of Eastern Riverside and San Bernardino Counties in the Riverside MSA. We also exempted whole counties in the Dallas, Cincinnati, and Kansas City MSAs. We determined that these areas had low population densities relative to other parts of the MSA and that the allowed charges for DMEPOS items attributed to these areas were low relative to the MSA as a whole indicating that the areas were not competitive when compared to other parts of the MSA. We will use a similar process to determine which areas might be exempted during Round 2.

2. What factors will CMS use to determine when and how it will exercise its authority under Social Security Act (SSA) § 1834(a)(1)(F)(ii) (for DME), SSA § 1824(h)(I)(H)(ii) (for off-the-shelf orthotics), and SSA § 1842(s)(3)(B) (for enteral nutrients, supplies, and equipment), which allow the agency to apply prices from winning bids in other MSAs around the country to rural areas?

   **Answer:** In a final rule, we stated that we would develop a more detailed plan and conduct subsequent rulemaking prior to using these authorities.

**Rep. Sam Johnson**

1. In the Final Rule issued April 2, 2007, CMS permits physicians to furnish certain types of competitively bid items without submitting a bid and winning a contract. These items include crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors and infusion pumps, but do not include off the shelf orthotics. However, the rule does allow physical and occupational therapists to provide off the shelf orthotics to their patients without participating in competitive bidding because "we have determined that these items would ordinarily be furnished as an integral part of occupational or physical therapy services." Why is there a separate standard for physicians and physical therapists and is there a legitimate concern that this may compromise the ability of physicians to provide medically necessary orthotics to their patients. Why did CMS choose to create a separate standard for physicians and is the agency considering a way to correct this problem?

   **Answer:** We received comments in the DMEPOS Competitive Bidding Program proposed rule that physicians and treating practitioners should be exempted from the competitive bidding program for certain DMEPOS items. We also received comments that physical therapists and occupational therapists should be exempted from participating in the program because these health care professionals are licensed by State boards.

   In the final rule, we stated that physicians and treating practitioners are exempt from competitive bidding for crutches, canes, walkers, folding manual wheelchairs, and blood glucose monitors if furnished to their patients as part of their professional service. A similar exemption applies to physical therapists and occupational with respect to off-the-shelf (OTS) orthotics if furnished to their patients as part of their professional service. This condition applies for OTS orthotics because these items are ordinarily furnished as an integral part of occupational therapy and physical therapy services.

2. The Final Rule requires physicians to become accredited in order to supply any orthotics to their patients in the Medicare program. Due to the cost and paperwork required it is likely that many physicians will likely choose not to become accredited, this will then raise some questions about how beneficiaries will receive medically necessary orthotics. In a separate rule relating to Medicare DMEPOS supplier standards released on January 25, 2008, the agency proposes an across-the-board prohibition on suppliers sharing a practice location with other suppliers—including physicians and other health are practitioners. Physicians at times need to dispense medically necessary DMEPOS items immediately to a Medicare beneficiary—like stabilizing braces, or immobilizing devices. Isn't there a concern that this proposed rule, when considered in conjunction with the new requirements on physicians under competitive bidding, could deny Medicare beneficiaries the ability to receive these medically necessary items when they need them?

   **Answer:** It is important that Medicare beneficiaries are able to receive the medically necessary items they need. It is equally important to protect our beneficiaries from fraudulent actors. CMS considers both these factors when developing its policies.

The Medicare Modernization Act of 2003 required that CMS establish quality standards for suppliers of DMEPOS items to be applied by recognized independent accreditation organizations and that such supplier shall be required to comply with these standards in order to furnish these items and receive or retain a billing number. CMS does not have the authority to exempt supplier groups and therefore physicians are required to be accredited if they supply a DMEPOS items.

The provision in the Medicare DMEPOS supplier standards rule released on January 28, 2008 is a proposed provision that prohibits suppliers from sharing practice locations with other suppliers. In this proposed rule, we asked for comments on possible exceptions to this rule for physicians and nonphysician practitioners and the circumstances that warrant an exception. Comments were due on March 25, 2008 and we are reviewing the comments received as we finalize the rule.